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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,261	12/03/2003	Herbert W. Harris	18184-0004 US	7783

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
04/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,261	HARRIS ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12 and 33-36* is/are allowed.

6)☒ Claim(s) *22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 16, 2009 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of March 16, 2009 made to the office action filled December 16, 2008. Claims 1-12, 22-25 and 33-36 are pending. Claims 13-21, 26-32 and 37-58 are cancelled. Claims 22-25 and 33-36 are amended.

In light of the cancellation of claims the double patenting rejection of claims 13-18 over, U.S. Patent No. 6,864,251 B2 and 6,638,928 B1 is withdrawn.

In light of the cancellation of claims the obviousness-type double patenting rejection of claims 13-17 over copending Application No. 10/578,522, is withdrawn.

In light of the cancellation of claims, the 35 U.S.C. 112, first paragraph rejection of claims 13-21, 26-32 and 37-58 is withdrawn.

In light of the amendment to the claims, the 35 U.S.C. 112, first paragraph rejection of claims 33-36 is withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 112, first paragraph rejection of claims 22-25 were found not persuasive, thus the rejection is upheld.

Due to the amendment to the claims, the modified 35 U.S.C. 112, first paragraph rejection is made below. The Applicant's arguments in regards upheld rejections are addressed below.

Allowable Subject Matter

Claims 1-12 and 33-36 are allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of treating a thromboxan A_2-mediated disorder related to platelet aggregation. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 22 is drawn to "a method of treating thromboxan A_2-mediated disorder related to platelet aggregation in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of a composition according to claim 1 sufficient to inhibit thromboxan A_2-mediated platelet aggregation in said individual."

(2) The breadth of the claims:

Claims 22-25 embraces and reads on treating any thromboxan A_2-mediated disorder related to platelet aggregation. The specification does not enable the treatment of any thromboxan A_2-mediated disorder related to platelet aggregation.

(3) The state of the prior art:

The state of the art regarding preventing treating all thromboxan A_2-mediated disorders related to platelet aggregation is very low or do not exist. Vermylen et al. (Cardiovascular Drugs and Therapy, 1992, vol. 6, pp. 29-33) teaches thromboxan receptor antagonists (TRA) give a more reproducible and pronounced inhibition of platelet function and preliminary clinical trials seem to indicate that thromboxane receptor antagonism may be more effective antiplatelet therapy than thromboxan receptotor inhibitors. However, possible drawbacks of this class of compounds are represented by their competitive nature, which could lead to their displacement from receptors (see page 30, column 2, thromboxan receptor antagonists in its entirety).

(4) The predictability or unpredictability of the art:

The predictability of treating all thromboxan A_2-mediated disorders related to platelet aggregation is relatively low. As taught by Vermylen et al. TRA compounds may be more effective antiplatelet therapy than thromboxan receptotor inhibitors. Additionally, this type of compounds have drawbacks of being competitive, which can lead to displacement from receptors. Therefore, to one skilled in the art, treating all thromboxan A_2-mediated disorders related to platelet aggregation is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high as demonstrated by Vermylen et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treating all thromboxan A_2-mediated disorders related to platelet aggregation is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treat all or any thromboxan A_2-mediated disorder related to platelet aggregation. On page 46 of the specification, the Applicant demonstrated that the claimed compound binds to the TXA_2 receptor and demonstrates a 48.26% inhibition, but does not demonstrate the compound effectively treats any of the vast amount of disorders that are associated with the binding of the TXA_2 receptor. As taught by

Vermylen et al., TRA compounds may be more effective antiplatelet therapy than thromboxan receptor inhibitors. Additionally, this type of compounds have drawbacks of being competitive, which can lead to displacement from receptors. Thus, one skilled in the art is not enabled from the Applicant's specification to effectively treat any thromboxan A_2-mediated disorder related to platelet aggregation because prior art teaches that thromboxan receptor inhibitors may be more effective antiplatelet therapy than TSI, but TSI in general have been disappointing in regards to therapy. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read treating all thromboxan A_2-mediated disorders related to platelet aggregation. As discussed above the specification fails to provide any support for effectively treating any thromboxan A_2-mediated disorder related to platelet aggregation. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable. One skilled in the art would need to first establish that the Applicant's claimed compounds is actually effective in treated any thromboxan A_2-mediated disorder related to platelet aggregation.

In conclusion, the applicant is enabled for inhibiting TXA_2 with the claimed compound, but not for treating all or any thromboxan A_2-mediated disorder related to platelet aggregation.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that the present compounds work by antagonizing the binding of TXA_2 to its receptor, and that Vermylen reports that TXA_2 receptor antagonists generally inhibit platelet function more reproducibly. Second, the artisan would expect compounds that antagonize the platelet TXA_2 receptor to have some ability to treat a TXA_2 mediated disorder related to platelet aggregation, irrespective of results in clinical trials. Further the applicants have proved working examples as an *in vitro* antagonism of the platelet TXA_2 receptor to correlate reasonably with inhibition a platelet aggregation.

The Examiner disagrees because Vermylen report that thromboxan receptor antagonist may be more effective antiplatelet therapy than TSI, but TSI in general have been disappointing in regards to therapy. Further Vermylen suggests combining thromboxan receptor antagonist and inhibitors may be a more ideal approach because of the observed drawbacks of each class of compounds (see page 31, column 1, lines 1-10). Thus, one can not expect that all thromboxan receptor antagonist will be effective in treating all TXA_2 mediated disorder related to platelet aggregation. Therefore, the *in vitro* results merely exhibit that the compounds are thromban receptor antagonist but not as effective in treating any or all TXA_2 mediated disorder related to platelet aggregation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617